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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,775	09/16/2002	Norman Latov	61546-A-PCT-US/JPW/FHB	2322
7590	04/07/2004		EXAMINER	
John P White Cooper & Dunham 1185 Avenue of the Americas New York, NY 10036			GRUN, JAMES LESLIE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
10/088,775	LATOV ET AL.	
Examiner	Art Unit	
James L Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 04 December 2003.  
2a) This action is FINAL.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-4 and 7-35 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 1-4 and 7-35 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 04 December 2003 is acknowledged and has been entered. Claims 5 and 6 have been cancelled. Claims 1-4 and 7-35 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-4 and 10-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2 and claims dependent thereupon, recitations of "type of ganglioside" are vague and indefinite as to what is intended as encompassed. It is not clear if a particular ganglioside or a group of gangliosides are intended and it is not clear, if a group is intended, how one determines members of the same "type."

Claims 1-3, 10, and 14-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Uhlig et al. (Autoimmunity 5: 87-99, 1989) for reasons of record taken further in light of the notoriously old and well known properties of the reagents of Uhlig et al. as taught in Beltz et al. (U.S. Pat. No. 4,753,873).

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Claims 1-3, 10, 13, 14, 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Uemura et al. (Biochem J. 219: 865, 1984) for reasons of record taken further in light of the notoriously old and well known properties of the reagents of Uemura et al. as taught in Beltz et al. (U.S. Pat. No. 4,753,873).

Claims 1-3, 10, 13, 14, and 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Uemura et al. (Biochem. J. 219:865, 1984) in view of Ravindranaths et al. (J. Biol. Chem. 263:2079, 1988) for reasons of record and further in view of the notoriously old and well known properties of the reagents of the references as taught in Beltz et al. (U.S. Pat. No. 4,753,873).

Claims 1-4 and 7-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Uhlig et al. (Autoimmunity 5: 87-99, 1989) in view of Dwyer et al., Uemura et al. (Biochem. J. 219:865, 1984), Ravindranaths et al. (J. Biol. Chem. 263:2079, 1988), Pestronk (U.S. Pat. No. 5,443,952), and applicant's admissions regarding the prior art for reasons of record and further in view of the notoriously old and well known properties of the reagents of the references as taught in Beltz et al. (U.S. Pat. No. 4,753,873). In addition to the reasons set forth previously, it would have been further obvious to have determined the titers of antibodies to glycolipids with a notoriously old and well known technique such as serial dilutions of sample, which was known for the detection of autoantibodies which bind gangliosides by agglutination assays as taught in Uemura et al., because Pestronk and applicant's admitted prior art teach determination of

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antibody titer and one would have been motivated to use a conventional method therefor applicable to the selected detection assay.

In addition to the reasons of record set forth in the previous Office action, Beltz et al. teach that suitable solid particles for agglutination assays can be for example, latex, red blood cells, or liposomes, and that agglutination of such particles can be detected with a technique such as nephelometry (see e.g. col. 9, lines 17-25, and col. 20, claim 8). Thus, in light of and/or in view of these teachings the reagents of the prior art clearly meet the limitations as instantly claimed wherein use of a solid particle is required.

Applicant's arguments filed 04 December 2004 have been fully considered but they are not deemed to be persuasive. Applicant's argument regarding the properties of the reagents of the prior art were not found persuasive in view of what was notoriously old and well known in the art in light of and/or in view of the teachings of Beltz et al. as set forth in the new grounds of rejection. Applicant urges that Dwyer et al. is non-analogous art. This is not found persuasive because the reference is clearly concerned with presenting a glycolipid binding ligand to binder and providing a visible indication of the binding interaction via agglutination as set forth. Applicant urges that nephelometry is not specific for agglutination assays. This is not found persuasive in view of what was notoriously old and well known in the art in light of and/or in view of the teachings of Beltz et al. as set forth in the new grounds of rejection that nephelometry was well known for determinations of agglutination assays. Notwithstanding applicant's

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implication to the contrary, Pestronk is not being relied upon as a sole reference for making obvious determination of antibody levels specific for glycolipids by agglutination assay.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

*JL*  
James L. Grun, Ph.D.  
April 2, 2004

*Christopher L. Chin*  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1641